005_510(k) Summary (Revised)

[807.92(c)]

vidacare

4350 Lockhill Selma Road
Shavano Park, TX
78249+2095
210-375-8500
www.vidacare.com

SUMMARY (Revised)

Submitter's name [807.92(a)(1)]: Vidacare Corporation

Address: 4350 Lockhill Selma Road

Shavano Park, TX 78249-2095

Phone: 210-375-8500

Fax number: 210-375-8537

Name of contact person: Larry Miller, MD, CMO/ Diana Montez, BSN, RN

Date Summary was prepared: October 30, 2013

[807.92(a)(2)]:
Trade Name of the devices: EZ-IO Intraosseous Infusion System
Common or usual name: Intraosseous Infusion System
Classification name: Hypodermic single lumen needle

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

510(k) number	***Trade or Proprietary or Model Name***	***Manufacturer***
K091140	EZ-MIO Distal Tibia, EZ-IO Distal Tibia; EZ-IO (formerly Vidaport) Intraosseous Infusion System; EZ-IO Humeral Head	Vidacare Corporation
K101026	Powered PD IO Infusion System; EZ-IO Humeral Head; Powered PD-IO	Vidacare Corporation

510(k) number	*Trade or Proprietary or Model Name*	*Manufacturer*
K981853 K062940	Bone Injection Gun™ Adult Proximal Tibia Humeral Head	Waismed
K915409 K913258	Cook Intraosseous Infusion Needles	Cook Medical Inc

Device Description [807.92(a)(4)]:

The EZ-IO Intraosseous Infusion System including previously cleared K091140 EZ-MIO Distal Tibia, EZ-IO Distal Tibia; EZ-IO (formerly Vidaport) Intraosseous Infusion System ; EZ-IO Humeral Head and K101026 Powered PD IO Infusion System; EZ-IO Humeral Head; Powered PD-IO is designed to allow the user to insert a needle set consisting of a stylet and catheter through the cortex of the bone to a desired depth within the bone marrow to facilitate intraosseous infusion of desired fluids for vascular access. All system materials are medical grade. Needle sets are single-use and composed of 304 stainless steel with polycarbonate hubs and available in 15 mm (3-39 kg); 25 mm (40 kg or over) and 45 mm (40 kg or over). Black lines on the needle set catheter serve as depth markers. The needle sets connect to the driver/drill/ manual handle shaft with a magnetic disc. The reusable cordless driver/drill is powered by lithium batteries with a battery-power indicator light. The EZ-MIO consists of a manual handle device which is primarily used by the armed forces.

Clinicians locate anatomical landmarks and clean the insertion site. Using the cordless driver or manual handle with needle set attached the needle set is pressed through the soft tissue to the outer cortex of the bone. Depth markers on the catheter must be visible prior to powering driver or manually inserting the needle set to ensure placement within the medullary space. If using the powered driver clinicians then squeeze the driver trigger and apply moderate, steady pressure. Trigger is released when a sudden "give" or "pop" is felt, which indicates entry into medullary space; the catheter will not always be inserted to the hub. If using the manual handle, clinicians apply downward pressure and rotation through the bone until a change in pressure is felt as a "give" or "pop" or desired depth is reached. For both methods after insertion of the needle set, the driver unit is detached from the needle set, leaving the stylet and cannula firmly seated in the bone. The stylet is then separated and removed from the catheter by turning the stylet hub counter clockwise leaving a standard Luer lock catheter securely seated in the bone. The catheter Luer lock permits attachment of standard syringes and IV tubing for administration of medications and fluids.

This submission requests a label change only to the 25 mm needle set from "40 kg or over" to" 3 kg or over" utilizing the same technique and devices previously cleared via 510(k)s K091140 and K101026.

Proposed Expanded Weight Range for the 25 mm needle set:

Vidacare is requesting a label change only to the 25 mm needle set from "40 kg or over" to "3 kg or over" to provide clinicians with an option to choose the correct needle length not only based on weight but also variability in each patient's anatomy. Due to differences in the amount of soft tissue overlying the target anatomical area, many patients less than 40 kg require additional needle length the 25 mm offers over the 15 mm needle length. This has been noted by authors in a clinical study which stated the limiting factor for successful insertions is the amount of tissue covering the approved insertion site.[1] Cadaveric pediatric studies with representative photographs demonstrate the 25 mm length to be safe and often necessary in patients less than 40 kg (see RTA response section J_number 36_Performance Data included with this response package). There would be no change in the Directions for Use as insertion technique is the same.

In consideration of our cited predicate similarities, performance data, observations noted in the cited clinical studies and Vidacare's experience with the EZ-IO Intraosseous Infusion System we conclude that expanding the weight range for the 25 mm needle set is a safe and correct modification. This modification will allow clinicians to choose the correct needle length based on the best anatomical site option, soft tissue depth over the insertion site with a wider weight range that more accurately suits patients' anatomy and needs, with a weight range of 3 kg or over .

1. Frascone RJ, Jensen J, Wewerka SS, Salzman JG. Use of the pediatric EZ-IO needle by emergency medical services providers. *Pediatric Emergency Care* 2009;25(5):329-32.

[807.92(a)(5)]:

(Proposed)Indications for Use:

The EZ-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

The above proposed Indications For Use provide the same indication as the predicate devices but is presented in a condensed version.

[807.92(a)(6)]:

Summary of the technological characteristics of our device compared to the predicate devices:

The labeling change requires no new technology to facilitate the safe application of the product. There have been no changes to the design or components of the Vidacare devices cleared under K091140 and K101026 and therefore, the comparison of technological characteristics listed below are identical:

- Target Population
- Driver Design Features
- Needle Design
- Technique
- Anatomical Sites
- Sterility
- Biocompatibility
- Where Device is Used (types of facilities/environments)
- Types of Clinicians (that would use device)

For predicates K981853, K062940 The Bone Injection Gun and K915409, K913258 Cook Intraosseous Infusion Needles the following characteristics are similar or identical:

- Target Population
- Needle Design
- Technique:
  - For insertion -Cook and EZ-MIO devices
  - For locating correct sites; validating insertion; indications and contraindications
- Anatomical sites
- Sterility
- Biocompatibility
- Where Device is Used (Types of facilities/environments)
- Types of Clinicians (that would use device)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

Vidacare Corporation
Dr. Larry Miller
CMO
4350 Lockhill Selma Road
Shavano Park, TX 78249

Re: K132583
Trade/Device Name: EZ-IO Intraosseous Infusion System
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: August 19, 2013
Received: August 21, 2013

Dear Dr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

Indications for Use

510(k) Number (if known): K132583

Device Name:

The EZ-IO Intraosseous Infusion System provides intraosseous access in the proximal tibia, distal tibia and humeral head (proximal humerus) of adult and pediatric patients when intravenous access is difficult or impossible to obtain in emergent, urgent, or medically necessary cases for up to 24 hours.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA

Digitally signed by
Richard C. Chapman
Date: 2014.02.10
16:20:00 -05'00'